

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Robert R. Neall, Secretary

Laboratories AdministrationRobert A. Myers, Ph.D., Director
1770 Ashland Avenue
Baltimore, Maryland 21205

DATE: March 3, 2020

TO: Medical Laboratory Directors, Local Health Officers, and Health Care Providers

FROM: Robert A. Myers, Ph.D.

Director, Laboratories Administration

RE: Updated Interim Guidance and Instructions for Submission of Specimens for Suspected

COVID-19 Infections: Testing at the Maryland Department of Health (MDH) Laboratory

Effective today, Tuesday March 3, 2020, the Maryland Department of Health (MDH) Laboratory will begin to perform the CDC developed 2019-Novel Coronavirus (2019-nCoV) Real-time RT-PCR Diagnostic Panel which is approved by the FDA under an Emergency Use Authorization (EUA) for the detection of nucleic acids of 2019-nCoV (now designated SARS-CoV-2) from upper and lower respiratory tract specimens collected from individuals who meet the current CDC criteria for COVID-19 testing. https://www.cdc.gov/coronavirus/2019-nCoV/clinical-criteria.html

An infectious disease consultation with a Local Health Department or MDH epidemiologist is still required to authorize specimens for 2019-nCoV testing at the MDH Laboratory prior to submitting specimens. This consultation will determine if the suspect case meets the clinical criteria that would qualify the patient for testing. Contact your Local Health Department, or if they are not available, the MDH Infectious Disease Epidemiology and Outbreak Response Bureau at (410) 767-6700 (or after hours, at (410) 795-7365) to arrange for consultation with an epidemiologist. Additional testing for more common respiratory pathogens (e.g., seasonal influenza viruses) may also be performed in parallel at the MDH Laboratory to assist in establishing a diagnosis.

Do not collect and submit specimens to the MDH Laboratory until an infectious disease consultation with the MDH physician-epidemiologist has been conducted and approval has been obtained to provide testing for the case. For detailed information on test ordering, specimen collection, proper packaging and shipping of specimens for COVID-19 testing refer to the enclosed attachment or go to the MDH Laboratories Website at: https://health.maryland.gov/laboratories/Pages/Novel-Coronavirus.aspx

For more information regarding the performance characteristics of the 2019-Novel Coronavirus (2019-nCoV) Real-time RT-PCR Diagnostic Panel see fact sheets below:

Fact Sheet for Healthcare Providers: CDC-2019-nCoV Real-Time RT-PCR Diagnostic Panel https://health.maryland.gov/laboratories/docs/Fact%20Sheet%20for%20Healthcare%20Providers%20CD C-2019-nCoV%20Real-Time%20RT-PCR%20Diagnostic%C2%A0Panel%C2%A0.pdf

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Fact Sheet for Patients: CDC-2019-nCoV Real-Time RT-PCR Diagnostic Panel https://health.maryland.gov/laboratories/docs/Fact%20Sheet%20for%20Patients%20CDC-nCoV%20Real-Time%20RT-PCR%20Diagnostic%C2%A0Panel.pdf

For additional questions or concerns about COVID-19 testing at the MDH Laboratory please contact the Division of Molecular Biology Laboratory at 443-681-3924 or 443-681-3800 during normal business hours from 8:00AM-4:30PM.

cc: Frances Phillips

Dr. David Blythe

Dr. Monique Duwell

Dr. Cliff Mitchell

Dr. Richard Brooks

Ruth Thompson

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MDH Laboratories Administration: Coronavirus (COVID-19) Specimen Collection and Shipping Guidance

Specimen Types - Collection of two specimen types, lower respiratory and upper respiratory, is recommended. Please collect an additional Nasopharyngeal swab (NPS) in a separate tube of viral transport media for respiratory pathogen testing at the MDH Laboratories Administration. Specimens should be collected as soon as possible once a PUI is identified regardless of symptom onset. Maintain proper infection control when collecting specimens. Refer to chart below for collection and storage instructions.

Specimen Type	Specimen Collection & Storage Instructions
Lower Respiratory (sputum, bronchoalveolar lavage, and tracheal aspirate)	For bronchoalveolar lavage and tracheal aspirates collect 2-3 ml into a leak-proof, sterile, screw cap sputum collection cup or sterile dry container. Refrigerate at 2-8°C and ship on ice pack to the Maryland Department of Health Laboratory. For sputum collections, have the patient rinse their mouth with water and then expectorate deep cough sputum directly into a leak-proof, sterile, screw cap sputum collection cup.
Upper respiratory (nasopharyngeal swab (NPS) and oropharyngeal swab (OPS)	Collect a nasopharyngeal swab and an oropharyngeal swab in separate viral transport media tubes (2-3ml). Use only synthetic fiber swabs with plastic shafts. Do not use calcium alginate swabs or swabs with wooden shafts as they may inhibit PCR testing or inactivate some viruses. Place swabs, after collecting patient specimen, directly into 2-3 ml of viral transport media. NP and OP specimens must be placed in separate vials. Refrigerate at 2-8°C and ship on ice pack to the Maryland Department of Health Laboratory.
Nasopharyngeal Wash/Aspirate or Nasal Aspirate	For NP wash/aspirate or nasal aspirate, collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container. Refrigerate specimen at 2-8°C and ship on ice pack to the Maryland Department of Health Laboratory.

Specimen collection kits (Viral Culture Kit) can be ordered by the local health department by calling 443-681-3777 and submitting via email or fax the Outfit Supply Requisition form. (See link below)

 Outfit Supply Requisition 2019 Fillable Form: https://health.maryland.gov/laboratories/docs/Outfit%20Supply%20Requisition%202019 %20Fillable%20Form%201019%20(1).pdf Medical Laboratory Directors, Local Health Officers and Health Care Providers March 3, 2020 Page 4

Completing the MDH Laboratory Test Request Form

The MDH Laboratories Administration Form # 4676 Infectious Agents: Culture /Detection must be completed and submitted with each of the recommended specimens (1) lower respiratory and (2) upper respiratory.

Click on the examples of the completed form #4676 and the electronic fillable form.

- Lab Requisition Sample Completed Form (#4676): https://health.maryland.gov/laboratories/docs/2019%20Novel%20Coronavirus%20Training%20Requisition%201-2020.pdf
- <u>Electronic Fillable Lab Requisition (#4676):</u>
 https://health.maryland.gov/laboratories/docs/MDH%204676%20Infectious%20Agents%20Culture%20Detection%20Training%20Form%20Fillable%201-2019.pdf

Packaging and Shipping

Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to page 9 in the Lab Services Guide)

Packaging and Shipping Guide (Pages 9 to 11)
 https://health.maryland.gov/laboratories/docs/Guide%20to%20PH%20Lab%20Serv%20v2.0.8%2
 02018%20Guide%20Updated%204-2018%20Final.pdf#page=9

Contact Information:

To request COVID-19 testing for a suspect case, health care providers must contact the MDH Infectious Disease Bureau at 410-767-6700 during business hours and after hours call the MDH Emergency Call Center at 410-795-7365 to arrange the initial disease consultation.

For questions or concerns, please contact the Division of Molecular Biology Laboratory at 443-681-3924 or 443-681-3800 during normal business hours from 8:00AM-4:30PM.